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An Independent Review Organization

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Case Number:

Date of Notice: 11/13/2015

Review Outcome:

A description of the qualifications for each physician or other health care provider who reviewed the decision:

Orthopedic Surgery

Description of the service or services in dispute:

C6/7 Total Disc Replacement

Upon Independent review, the reviewer finds that the previous adverse determination / adverse determinations should be:

- ☒ Upheld (Agree)
- ☐ Overturned (Disagree)
- ☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)

Patient is an individual. On 08/05/15, an MRI of the cervical spine was obtained noting at C6-7, there was a posterior 1-2mm disc protrusion, contacting the thecal sac without significant neuroforaminal narrowing. At C4-5 there was a posterior 1-2mm disc protrusion pressing on the thecal sac without narrowing. No facet disease was identified and the cervical spinal cord was unremarkable. On xxxxxx neuroforaminal, the patient was seen in clinic. It was noted she had undergone a cervical epidural steroid injection, and had constant headaches, neck pain, and dizziness. On exam, Spurling's sign reproduced symptoms to the left upper extremity, and motor strength was weakened in shoulder abduction, wrist flexion and wrist extension on the left. She had paresthesias along the 1st and 2nd digits of the left hand and reflexes were 1-2+. On 08/18/15, the patient returned to clinic. Pain was rated at 6/10. On exam, reflexes were 1-2+ in the upper extremities, the patient had mild paresthesias in the 1st and 2nd digits of the left hand, and motor weakness was noted in shoulder abduction, wrist flexion and in wrist extension on the left. Spurling's sign reproduced symptoms to the left upper extremity. A C6-7 total disc replacement was recommended.

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

On 09/30/15, a utilization review report noted the request for a C6-7 total disc replacement was not medically necessary, as the patient had disc disease at more than 1 level as demonstrated on exam and imaging, and the request was not considered medically necessary. On 10/02/15, a letter was submitted noting the request was non-certified for appeal for a C6-7 total disc replacement. The decision was based on Official Disability Guidelines neck chapter. On 09/03/15, a utilization review report noted the requested C6-7 total disc replacement was not medically necessary, and the rationale was based on the Official Disability Guidelines neck chapter, in which it was noted imaging did not show significant nerve root compression, and there is no significant stenosis, and the evidence based guidelines do not recommend the procedure given the multiple levels of disc degeneration.

The guidelines state this procedure is under study, with recent promising results in the cervical spine. The general indications for currently approved cervical-ADR devices (based on protocols of randomized-controlled trials) are for patients with intractable symptomatic single-level cervical DDD who have failed

at least six weeks of non-operative treatment and present with arm pain and functional/ neurological deficit. The patient, per imaging, has multi-level degenerative disease of the cervical spine.

It is the opinion of this reviewer that the request for a C6-7 total disc replacement is not medically necessary and the prior denials are upheld.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ☐ ACOEM-America College of Occupational and Environmental Medicine um
- ☐ knowledgebase AHCPR-Agency for Healthcare Research and Quality Guidelines
- ☐ DWC-Division of Workers Compensation Policies and
- ☐ Guidelines European Guidelines for Management of Chronic
- ☐ Low Back Pain Interqual Criteria
- ☒ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical
- ☐ standards Mercy Center Consensus Conference Guidelines
- ☐ Milliman Care Guidelines
- ☒ ODG-Official Disability Guidelines and Treatment
- ☐ Guidelines Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and Practice
- ☐ Parameters Texas TACADA Guidelines
- ☐ TMF Screening Criteria Manual
- ☐ Peer Reviewed Nationally Accepted Medical **Literature** (Provide a description)
- ☐ Other evidence based, scientifically valid, outcome focused guidelines (Provide a description)